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Dated: September 4, 2009

Electronic Signature for Todd W. Wight: /Todd W. Wight/

Docket No.: 1016760061P

PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:
Douglas G. EVANS, et al.

Application No.: 10/633,254

Confirmation No.: 4792

Filed: August 1, 2003

Art Unit: 3773

For: SELF-ANCHORING SLING AND
INTRODUCER SYSTEM

Examiner: J. W. Woo

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REPLY BRIEF

This is a Reply Brief filed under 37 CFR § 41.41 in response to the Examiner's Answer, mailed July 7, 2009 in the above-referenced application. An optional reply is due September 7, 2009; accordingly, this brief is timely filed. Appellant addresses points raised by the Examiner and continues to rely on its arguments in the Appeal Brief.

I. STATUS OF CLAIMS

The Examiner agreed that the following statement of the status of the claims contained in the brief is correct. Claims 1-4 and 120-132 are pending in this application. Claims 1-4 and 120-132 are finally rejected and on appeal. Claims 5-119 have been cancelled and are not on appeal.

The Examiner agreed that the following statement of the status of amendments after final rejection contained in the brief is correct. Claims 35 and 36 were previously pending in the application, and were cancelled in the response to final Office Action, dated August 12, 2008. New claim 132 was filed in the response to final Office Action including the subject matter of independent claim 35 and dependent claim 36. Pursuant to 37 CFR § 1.116, Appellant believes new claim 132 presents the previously rejected claims 35 and 36 in a better form for consideration on appeal. In an Advisory Action, dated August 26, 2008, the amendments were entered and an explanation of how the new claim would be rejected was provided.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- A. Whether claims 1-4, and 120-123, 125-128, and 131-132 are unpatentable under 35 U.S.C. § 103 over Staskin in view of Richmond?
- B. Whether claim 124 is unpatentable under 35 U.S.C. § 103 over Staskin in view of Richmond, and further in view of Smith?
- C. Whether claims 129 and 130 are unpatentable under 35 U.S.C. § 103 over Staskin in view of Richmond, and further in view of Gellman?

III. RESPONSE TO EXAMINER'S ARGUMENTS

A. Whether claims 1-4, 120-123, 125-128, and 131-132 are unpatentable under 35 U.S.C. § 103 over Staskin in view of Richmond?

1. Claims 1-3, 120-123, 125-128, and 131

Staskin fails to disclose a first arm and second arm pivotally mounted to the central portion. The Examiner asserts, at page 6 of the Answer, that the central portion is a flexible hinge between 112' and 54b; and therefore, since the central portion is a flexible hinge, both arms (54A or 54B and 112 or 112') are capable of pivotal movement relative to the central portion. However, the Examiner has failed to identify a connector including "a central portion," and "a first arm pivotally mounted to the central portion," and "a second arm pivotally mounted to the central portion." Essentially, the Examiner has asserted that the central portion is a pivot that is pivotally mounted to itself, and has thereby eliminated the element of a central portion from claim 1.

Claim 1 recites that both a first arm and a second arm are pivotally mounted to the central portion. The central portion cannot be the hinge creating the pivotal mount, because this arrangement only permits the alleged first and second arms to be pivotally mounted with respect to *each other* rather than the central portion, and essentially eliminates the element of the central portion from the claim. "Pivotally" is defined as "of, relating to, or constituting a pivot."¹ From this definition, "pivotally mounted," as between the first arm and the central portion, constitutes a pivot, and "pivotally mounted," as between the second arm and the central portion, constitutes a pivot. Claim 1 recites a pivot between the first arm and the central portion, and a pivot

¹ Merriam-Webster on-line dictionary, "pivotally," <http://www.merriam-webster.com/dictionary/pivotally>, Aug. 19, 2009

between the second arm and the central portion. As such, the Staskin central portion cannot be the hinge creating the pivotal mount as asserted by the Examiner.

2. Claim 4

The Staskin disclosure is not sufficiently enabling prior art to show a needle with a flared section having a cross-sectional profile that, in a given direction, is at least as large as a cross-sectional profile of the connector in the given direction as recited in claim 4. The Examiner asserts that the Staskin needle includes a flared portion adjacent to element 60A that has a cross-sectional profile at least as large as a cross-sectional profile of the connector. However, the Examiner merely references FIG. 16A and asserts that the limitation is met. First, the Examiner has misinterpreted the alleged feature. Further, without any disclosure within the specification or the drawings, Staskin is not enabled for the purposes of showing a needle with a cross-sectional profile at least as large as a connector cross-sectional profile. (*See*, MPEP § 2121.04 (a picture must show all the claimed structural features and how they are put together in order to be sufficiently enabling prior art)).

The Examiner alleges that Staskin includes a flared portion adjacent to element 60A. Nowhere does Staskin actually reference or describe the alleged feature, nor the relative profiles of the asserted flared section to the connector. Further, the Staskin FIG. 16A is ambiguous as to the actual feature referenced by the Examiner. From the Staskin specification, the alleged feature fits within the dilator as it is likely an additional mating surface for the dilator. For example, Staskin describes a dilator that fits over the needle using keying features to associate the dilator with the surgical needle. (*See*, Staskin, col. 18, l. 64 - col. 19, l. 11). The keying feature illustrated in FIG. 10 includes a shoulder on an internal lumen of the dilator to seat within a recess of the needle. (Staskin, col. 19, ll. 21-25). Staskin further describes other mechanisms

including bumps, grooves, slots, wedges, and tabs. (Staskin, col. 19, ll. 26-30). However, nowhere does Staskin suggest that these features are outside of the dilator. Instead, Staskin describes a through-hole that extends substantially internally along the longitudinal axis of the dilator that is configured for convenient attachment to the needle. (Staskin, col. 18, l. 64 - col. 19, l. 2). Further, the alleged flared section does not have any purpose as a flared section outside of the dilator as the dilator provides “a gentle transition between the diameter of the needle, to the shape of the dilator, and finally to the sling assembly 46.” (Staskin, col. 18, ll. 16-18). Therefore, the alleged flared section of the needle is positioned inside the dilator when connected together. Since the dilator passes over the needle, including the alleged flared section, the cross-sectional profile will always be smaller for the needle than the alleged connector. (Staskin, FIG. 12B, col. 20, ll. 49-50 (the first end of the needle is positioned within the dilator)).

Even assuming *arguendo* that Staskin shows a flared portion of the needle that might be outside of the dilator, the disclosure is not enabled for purposes of showing the relative cross-sectional profile of the needle to the alleged connector. Referring to FIG. 16A, Staskin illustrates “a slim, arc-shaped needle,” but does not show the connector. (Staskin, col. 10, ll. 22-23; FIG. 16A). Staskin does not show or describe the relative sizes of the needle to the connector. Staskin does describe the needle as “slim” (Staskin, col. 10, ll. 22-23) with a diameter that is small relative to the prior art to reduce tissue trauma (Staskin, col. 23, ll. 25-27). Further, the dilator includes a taper that cams tissue out of the path of the sling assembly as the sling assembly is inserted in the body. (Staskin, col. 19, lines 52-43). It is clear that the dilator is intended to move the tissue out of the path of the implant, and that the needle be slim to reduce tissue trauma. Therefore, it follows that the cross-sectional profile of the dilator is larger than the cross-sectional profile of the needle.

3. Claim 132

Staskin fails to disclose an integrally formed introducer needle including a first flat spatulated section connected to the curved portion by a flared section having a cross-sectional profile that covers a cross-sectional profile of the first flat spatulated section, as recited in claim 132. The Examiner asserts that Staskin discloses a flared section between elements 170 and 60A. However, Staskin fails to describe this alleged feature. The Examiner additionally asserts the connection of the first spatulated section *via* the flared section does not require a direct, or in-line connection, between the spatulated section and the curved portion. However, claim 132 does not recite a “connected via” as used by the Examiner, but a “connected to,” which is not shown or described by Staskin.

The Examiner alleges that Staskin includes a flared portion adjacent to element 60A. However, Staskin does not describe a flared section anywhere on its needle. Staskin does not reference the alleged feature, nor describe a flared section of the needle anywhere in the specification. As stated above, section III.A.2, the Staskin FIG. 16A is ambiguous as to the actual feature referenced by the Examiner. Therefore, Staskin fails to show or describe a flared section on the alleged needle. Further, given that Staskin fails to describe the alleged flared section, Staskin is not enabled to show the flared section having “a cross-sectional profile that covers a cross-sectional profile of the first flat spatulated section” as recited in claim 132. The relative cross-sectional profile of the alleged flat spatulated section and the alleged flared section are not clearly illustrated nor sufficiently described to determine a relative size of the cross-sectional profiles.

Even assuming *arguendo* that Staskin shows or describes a flared section in the needle, the flared section is not connected to the flat spatulated section as asserted by the Examiner.

Independent claim 132 recites “the first flat spatulated section connected to the curved portion by a flared section.” Referring to the Merriam-Webster on-line dictionary, “connected” is defined as “joined or linked together” while “to” is “used as a function word to indicate contact or proximity.”² Therefore, the flared section is a contact link between the first spatulated section and the curved section of the needle. The Examiner has impermissibly interpreted the claim as “connected via” to suggest that the alleged needle of Staskin meets the limitations of claim 132. However, “via” is defined as “by way of,” which does not indicate the contact that “connected to” requires.³ Since, as argued in the Appeal Brief, Staskin discloses an additional section between the alleged spatulated section and curved section by other than the alleged flared section, Staskin fails to disclose the connection as claimed. (*See*, Appeal Brief, § VII.A.3.a, p.12).

Staskin further fails to disclose an elastically-biased latch portion having a projection dimensioned and disposed in the housing of the handle. The Examiner alleges that FIGS. 18C-18E as well as col. 25, lines 4-17, disclose that the latch portion 198 includes spring 208, which biases projections in a housing that engage the flat spatulated section. Staskin actually describes the alleged projections as creating a non-square-shaped opening that rests in a recess 130 of the needle, and does not engage the flat spatulated section as alleged.

Referring to FIGS. 16A and 18B-E, Staskin describes a needle with a square-shaped portion 126 (the alleged flat spatulated section) and a recess 130. (Staskin, col. 23, ll. 41-49). When the needle is properly positioned within the handle, the yoke (including the alleged

² Merriam-Webster on-line dictionary, “connected,” <http://www.merriam-webster.com/dictionary/connected>; “to,” <http://www.merriam-webster.com/dictionary/to>, Aug. 20, 2009.

³ Merriam-Webster on-line dictionary, “via,” <http://www.merriam-webster.com/dictionary/via>, Aug. 20, 2009.

projections) receives the recess. (Staskin, col. 23, ll. 66 - col. 24, l. 6). When the assembly is locked, the spring forces the push button 202 locked to the yoke 204 away from the longitudinal axis of the device, causing the groove (the alleged projections) to create a non-square-shaped opening. (Staskin, col. 25, ll. 4-31). As described, the alleged projections could not engage the alleged flat spatulated section, as the alleged flat spatulated section is square-shaped and would therefore not fit in the described non-square shaped opening created by the alleged projections. Instead, it is the recess that rests against the alleged projections to lock the assembly during use. Thus, Staskin fails to show or describe an elastically-based latch portion having a projection to engage *the flat spatulated section*, as claimed.

B. Whether claim 124 is unpatentable under 35 U.S.C. § 103 over Staskin in view of Richmond, and further in view of Smith?

Appellant reiterates the arguments of the Appeal Brief that claim 124 is patentable over Staskin in view of Richmond, and further in view of Smith. *See*, Appeal Brief, § VII.B.

C. Whether claims 129 and 130 are unpatentable under 35 U.S.C. § 103 over Staskin in view of Richmond, and further in view of Gellman?

Appellant reiterates the arguments of the Appeal Brief that claim 129 and 130 are patentable over Staskin in view of Richmond, and further in view of Gellman. *See*, Appeal Brief, § VII.C.

D. Conclusion

Claims 1-4, and 120-132, subject to this appeal, are patentable for the reasons discussed in the Appeal Brief and the reasons discussed herein. In particular, the asserted combination of Staskin in view of Richmond does not establish a *prima facie* case of obviousness under 35 U.S.C. § 103.

Favorable action is solicited and a finding of patentability of claims 1-4, and 120-132 is respectfully requested.

Appellant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-2191, under Order No. 101676.0061P from which the undersigned is authorized to draw.

Dated: September 4, 2009

Respectfully submitted,

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